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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER KOHARSKI, CHRISTOPHER				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/008,415

Applicant(s)

MILLER ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8-12 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-12 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 11/07/2007 in which claims 1-3, 8, and were amended and new claims 20-22 were added. Currently claims 1-3, 8-12 and 17-22 are pending for examination in this application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukunaga et al. (5,582,596). Fukunaga et al. discloses an applicator for applying a biocompatible adhesive.

Regarding claims 1-3, 8, 17 and 22, Fukunaga et al. discloses an adhesive applicator system (Figures 1-3) comprising: a first syringe for storing a first solution (4); a second syringe for storing a second solution (4); a compressed gas source for providing compressed gas (67); and an applicator including: a manifold (20) the manifold including a housing and first and second tubes (27), the housing having proximal and distal ends and defining a cavity, the first and second tubes each defining a fluid lumen and extending distally beyond the distal end of the housing, the first and second tubes each defining an expulsion port (end of 27), the first and second tubes fluidly connected to respective first and second syringes for selectively receiving the first

and second solutions in a separated manner and delivering each solution to one of the expulsion ports through which the solutions separately exit the applicator without mixing prior to exit; and a mixing tip (21), the mixing tip including an open proximal end, an open distal end, a gas chamber (Figures 4-5), and a gas inlet (28), the mixing tip being mounted to the manifold housing at the proximal end of the mixing tip, wherein the first and second tubes extend through the gas chamber and extend distally beyond the open distal end of the mixing tip (Figures 4-5), the gas inlet member extends proximally from the mixing tip at an angle of less than 90 degrees and is adapted to deliver a source of compressed air to the gas chamber, the open distal end the expulsion ports further being provides for release of compressed gas around, adjacent to or proximate the expulsion ports (col 6, ln 1-15) such that the compressed gas when released mixes and propels the solutions and the compressed gas to a surgical site (Figures 1-13, cols 1-2).

***Claim Rejections - 35 USC § 102***

Claims 1-3, 8-12, 17-19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchida et al. (5,980,866). Uchida et al. discloses a tissue adhesive suitable for spray application.

Regarding claims 1-3, 8-12, 17-19 and 22, Uchida et al. discloses an adhesive applicator system (Figure 3) comprising: a first syringe for storing a first solution (5); a second syringe for storing a second solution (6); wherein the syringes are of differing sizes and volumes; a compressed gas source for providing compressed gas (col 6, ln 1-15); and an applicator including: a manifold (9) the manifold including a housing and first and second tubes (11, 12), the housing having proximal and distal ends and defining a

cavity, the first and second tubes each defining a fluid lumen and extending distally beyond the distal end of the housing, the first and second tubes each defining an expulsion port (end of 11, 12), the first and second tubes fluidly connected to respective first and second syringes for selectively receiving the first and second solutions in a separated manner and delivering each solution to one of the expulsion ports through which the solutions separately exit the applicator without mixing prior to exit; and a mixing tip (bottom of 9), the mixing tip including an open proximal end, an open distal end, a gas chamber (Figure 3), and a gas inlet (13), the mixing tip being mounted to the manifold housing at the proximal end of the mixing tip, wherein the first and second tubes extend through the gas chamber and extend distally beyond the open distal end of the mixing tip (Figure 3), the gas inlet member extends proximally from the mixing tip at an angle of less than 90 degrees and is adapted to deliver a source of compressed air to the gas chamber, the open distal end the expulsion ports further being provides for release of compressed gas around, adjacent to or proximate the expulsion ports (col 6, ln 20-35) such that the compressed gas when released mixes and propels the solutions and the compressed gas to a surgical site (Figures 1-3, cols 1-2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20 and 21 are rejected under 35 U.S.C 103(a) as being unpatentable over Fukunaga et al. (or Uchida et al.) in view of Zinger (5,810,885). Fukunaga et al. (or Uchida et al.) meets the claim limitations as described above except for the manifold and mixing tip being separate pieces.

However, Zinger teaches a device for applying one or several fluids.

Regarding claims 20 and 21, Zinger teaches an adhesive applicator system (Figure 1) comprising: a manifold (9) and a mixing tip (10) in which the manifold is insertable into the distal end of the mixing tip (Figures 1-2).

At the time of the invention, it would have been obvious to include the separate tip of Zinger to the system of Fukunaga et al. (or Uchida et al.) in order to allow for separation after use to facilitate cleaning and or clog removal. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Zinger (cols 1-2). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the manifold and mixing tip separate pieces, since it has been held that constructing a

formerly integral structure in various elements involves only routine skill in the art, see *Newin v. Erlichman*, 168 USPQ 177 (BdPatApp&Int 1969).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-3, 8-12 and 17-22 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

1/17/08



Christopher D. Koharski  
AU 3763

